MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
1300 Pennsylvania Avenue, N.W.
Washington, D.C.

Thursday, January 16, 2003

9:14 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair
ROBERT D. REISCHAUER, Ph.D., Vice Chair
NANCY ANN DePARLE
DAVID DURENBERGER
ALLEN FEEZOR
RALPH W. MULLER
ALAN R. NELSON, M.D.
JOSEPH P. NEWHOUSE, Ph.D.
CAROL RAPHAEL
ALICE ROSENBLATT
JOHN W. ROWE, M.D.
DAVID A. SMITH
RAY A. STOWERS, D.O.
MARY K. WAKEFIELD, Ph.D.
NICHOLAS J. WOLTER, M.D.

AGENDA ITEM:

Exploring alternatives to AWP-pricing for Medicare-covered drugs

-- Joan Sokolovsky

DR. SOKOLOVSKY: Good morning.

In the commission's October letter to CMS commenting on the proposed rule for the outpatient PPS, we stated that the current method by which Medicare pays for outpatient drugs covered under Part B leads to payments that far exceed provider costs. We noted that Congress and CMS have been considering ways of reforming the current system and that MedPAC would monitor the impact of any payment changes. Staff is also focusing its efforts on analyzing options for change.

Today, we plan to describe recent changes made by CMS to the payment system, discuss payment methods used by other payers, and finally look at some new developments in the private market.

Although Medicare covers relatively few outpatient drugs, both utilization and spending for these covered drugs have been growing rapidly. In fact, by more than 20 percent a year for the last three years. In 2001, Medicare spent more than $6.5 billion on Part B drugs and this total does not include drugs dispensed in outpatient apartments or in dialysis clinics.

As I'm sure you remember, Medicare reimburses providers at the rate of 95 percent of the average wholesale price or AWP. Under Part B drugs are generally provided by physicians in their offices or pharmacy suppliers when the drugs are used with durable medical equipment. Physician-billed drugs account for more than 75 percent of total Medicare expenditures for covered drugs and it's primarily the physician-billed drugs that we're going to be focusing on today.

I want to discuss one change that CMS has already implemented and then a couple of other things that the agency is doing that have implications down the road for the way in which Part B drugs will be paid for.

CMS recently implemented a change in the way payment rates will be calculated. Instead of having each carrier calculate AWPs, they have determined that there would be what they call a single national drug price or SDP. It will be determined for all carriers by one chosen carrier, Palmetto GBA. Medicare will still pay 95 percent of AWP and AWPs will still be calculated based on the same sources that all the carriers are currently using, red book and national databank, but it will be done by this one carrier with expertise in finding the AWP's and then all the carriers will use it.

CMS has estimated that this will save the program about $50 million annually. The policy will not affect drugs dispensed by outpatient departments or drugs purchased from pharmacy suppliers along with DME. The DME carriers have for awhile had one set of prices that all of the DME carriers use.

Establishment of the single drug price could create the infrastructure for further changes. In time the carrier -- and this is something that the CMS administrator discussed in

congressional testimony in October. In time the carrier could use a market survey to calculate AWPs based on what providers actually pay for the drugs. The agency has previously estimated that this approach could save about $500 million annually.

I want to briefly note, and these were not in your mailing materials, two other developments that could potentially have effects. Recently, on December 13th, CMS issued an interim final rule on inherent reasonableness. This establishes a process for changing prices if payment systems result in prices that are grossly deficient or excessive for an item or service covered under Part B and excludes physician services.

If the payment adjustment that would be required to make the payments more in accord with market prices exceeds $100 million per year, the change would have to go through a Federal Register process and there would be a public comment period of about 60 days.

Any changes would have to be made gradually over a course of a number of years depending on how much would be needed to get the price more in accord with market prices.

The second thing I wanted to call to your attention is something that happened in the outpatient rule. CMS determined that a particular drug that had received pass-through status, they used clinical criteria and established that this drug, which was a new rather expensive drug was what they called -- and this is a new term of art for CMS . They determined it was functionally equivalent to another drug that already been approved and so they set the pass-through payment at zero and are paying for that drug at the same price in which they pay for the older drug. This does not affect payment under Part B where it would still be reimbursed at 95 percent of AWP. But this sets a precedent that potentially could be used in other situations.

MR. HACKBARTH: Joan, the first part of that, the December 13th notice, so basically that just established a process for determining or applying inherent reasonableness? It was not specific to these drugs?

DR. SOKOLOVSKY: No, but it does specifically say that it can be applied for drugs.

Next, I'd like to talk about what private payers are paying for physician-billed drugs. But before I do that I need to spend some time talking about the kinds of drugs that we're talking about. And in the private market these drugs are usually referred to as specialty drugs.

Specialty drugs are obviously not exactly the same as Part B drugs and, in fact, they're such a new idea that they have many definitions. In general they're physician-billed drugs and other high cost injectables and they are the most rapidly growing portion of both the private as well as the public pharmaceutical market.

An estimated $19 million were spent on specialty drugs in 2001 which represents an increase of 24 percent over 2000. At this point they represent 11 percent of the U.S. pharmaceutical market. So this is a really rapidly growing piece of the pharmaceutical market.

DR. ROWE: I'm sorry, but $19 million could not possibly be

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DR. SOKOLOVSKY: $19 billion.

DR. ROWE: Oh, okay.

DR. SOKOLOVSKY: These are the drugs that are used treat cancer, AIDS, hemophilia, hepatitis C, MS, and anemia. And as I said, they're high cost drugs. They range in price from $5,000 to $25,000 per patient per year. They also require a lot of special handling. Each unit those needs to be individually prepared based upon the weight of the patient and the doctor's particular dosage instructions. They need to be refrigerated, many of them shipped quickly to prevent spoilage.

Because of the high cost many insurers require prior authorization before dispensing. And the drugs often have unpleasant side effects and patients need frequent monitoring to ensure both that the side effects don't require intervention and also to ensure that patients don't give up on lifesaving drugs because of the unpleasant side effects.

Why are these drugs growing so quickly? Well, partly because the number of people living with serious chronic conditions is rising and because of the development of new treatments for managing these diseases that didn't exist before. But the largest driving factor in increase in this particular kind of drug is the increase in the number of biotechnology drugs in the market.

80 biotechnology drugs have received FDA approval. There are many more in the pipeline. These are the kinds of breakthrough drugs that you read about, they actually fit into this category. Not only are they expensive initially but there is currently no FDA process for approving generic biologicals, so there is no reason to think that the price will go down in at least the foreseeable future.

At the same time as Dyckman & Associates did their survey on what private plans were doing about physician fees, we asked them to also ask health plans about how they paid for physician-billed drugs. This was a survey of 32 large health plans with a combined enrollment of 45 million lives. We asked them again what formula they were currently using to pay for coverage of physician-billed drugs and whether they anticipated making any changes in the formula.

The survey found that payment systems for these drugs were in a state of flux. Most of the plans, or at least half of them, either had just made some changes, were about to make some changes, or were at least considering changes. All plans reported pricing based on AWP but 11 have developed or are developing different methods for not all drugs but at least categories of drugs. Most paid as much or more than Medicare for physician-billed drugs and the pricing method, again variation was by the kinds of drugs, therapeutic class of drugs, when the drugs did.

As I said before, these payment methods are very much in a state of flux. It's because of the rapid growth in the utilization and spending for these drugs. What was a little piece of the health care pie is growing rapidly enough that plans are beginning to take more notice of them. And at the time of

the survey about having half of the plans had changed, were changing, or were evaluating their payment methods for 2003.

Lots of different strategies were discussed by the plans. Some were simply lowering the percentage of AWP that they were paying for particular drugs. Some were asking physicians to submit invoices and paying acquisition costs. Some were setting up group purchasing organizations to buy drugs for their physicians and then reducing the reimbursement level for physicians who purchase drugs outside of the group purchasing organizations.

The most common change we found was that plans were working on selective contracting for some particular categories of drugs. Selective contracting is a relatively new method for paying for drugs that depends upon new entities in the health care system. It is this new and rapidly growing market for providing specialty drugs, which has led to the growth of specialty pharmacies.

Specialty pharmacies developed as niche providers for one or small number of serious medical conditions. They tend to specialize in not a particular drug but a particular condition. Hemophilia was the first disease that specialty pharmacies got very much involved in. Currently about $7 billion or 30 percent of specialty drugs are dispensed through specialty pharmacies.

These are not just things that insurers use, they are things that physicians use to purchase drugs.

They have a great many differences with conventional pharmacies. First of all, they don't have to be buildings. They generally aren't brick and mortar pharmacies that you go into. Most of their work is done through mail order. These pharmacies have expertise in preparation, the management and the delivery of therapies associated with a particular disease. They have compliance programs to make sure that all of the kinds of prior authorizations and whatever forms are necessary are completed so that providers will be reimbursed for the cost of drugs and manufacturers will be paid for the drugs that they reimburse.

They have patient assistance programs. Some are developing disease management programs. Some of the specialty pharmacies have special relationships with particular manufacturers.

One of the problems that's been discussed with specialty pharmacies is that because they focus on specific diseases they may not able to monitor interactions between drugs taken for different conditions. They know very well what you're doing about one particular condition but will not necessarily know, if you have comorbidities, what other kinds of drugs you're taking.

A second way in which specialty drugs are being dispensed is through the large PBMs. Most of the bit PBMs have either purchased specialty pharmacies or are developing their own specialty pharmacies. Because they link purchase of specialty drugs with all the other drugs that they're covering for a particular payer, they are better able to track drug utilization. They also try to bring the tools that they use to manage expenditures for drugs and other settings to use of drugs in this particular setting.

Some have worried that the use of PBMs to pay for these drugs could result in the kinds of formularies where a doctor's

decision that a particular drug is needed for a particular disease may not been necessarily handled if there's a formulary that's set up that recommends a different drug.

The third model that seems to be growing in the private marketplace is that some health plans are taking over the management of specialty drugs. Some of them set up networks with different specialty pharmacies that monitor different diseases and then they do the administration that links the interactions between different drugs.

Based on the survey results it seems likely that more health plans will be moving in the direction of somehow working with the specialty pharmacies or PBMs.

I think this look at the private market for specialty drugs has some implications for our analysis of payment options for Medicare. The first thing that I think has to be stressed is that utilization of physician-billed drugs is going to continue to rise and rise rapidly. We need to get the payment system right.

Secondly, I think it's important to recognize that this is not a simple system. The drugs aren't simple and the methods for paying for them are not simple. We should be careful about developing a policy that pre-empts innovations in a marketplace that's changing so rapidly.

Finally, payment reform should consider the different categories of covered drugs and biologicals and consider when developing a policy whether different strategies may be appropriate for different categories of drugs.

I welcome your comments.

MR. HACKBARTH: Joan, this to me seems a bit reminiscent of our discussions of payment for new technology where we're troubled with the status quo and that outpatient pass-through system. But it's one things to be dissatisfied with the status quo. It's another thing to come up with an option that works for a program like Medicare.

I remember in our discussions of paying for technology we went out and surveyed private payers and delivery systems about what they did and then we had a discussion about how well or not well some of those methods would apply to a program like Medicare.

It seems like what we say here needs to be closely coordinated with that. Am I barking up to right tree here? Aren't a lot of issues the same?

DR. SOKOLOVSKY: Many of the issues are the same but I think because we are limiting it to a discussion of drugs and biologicals, we have concrete strategies out that are being tested and we can look at them for that reason.

MR. HACKBARTH: Strategies used by private payers that we do think --

DR. SOKOLOVSKY: By private payers and public payers.

MR. HACKBARTH: That will work for Medicare?

DR. SOKOLOVSKY: Potentially. We have something to analyze, I think.

MR. HACKBARTH: Just one other question about the context. When we did the survey you said that we found that most were

paying as much or more than Medicare?

DR. SOKOLOVSKY: Yes.

MR. HACKBARTH: That caught my ear because I had the impression from our previous discussions that we were sort of the lone cowboys, the last to figure out that this was a problem.

MS. DePARLE: We definitely had that discussion, Glenn. And in fact, I remember -- I could be misremembering, but I thought back in 2000 or so there were inspector general reports and maybe other reports that basically said that. So I was very surprised when Zachary's information showed they were using AWP.

DR. ROWE: I think before we thought you were the lone cowboys. Now the situation has changed to the point where you're the lone cowboys and you don't know it.

DR. SOKOLOVSKY: The difference here, I think, is that these are not what providers are paying for these drugs. Providers are paying less for these drugs. But just as in Medicare, most insurance plans that have not moved to these new systems are third-party payers. They reimburse on the basis of a formula which, as in Medicare, is irrelevant what the provider paid. And they don't get the discounts and the rebates that a provider may or may not get.

MS. DePARLE: You're right. I'm not sure that the IG reports actually went to the issue of what do other payers pay. That's what was interesting, new information out of the report that we commissioned, I thought.

DR. MILLER: If I could clarify, don't some of those reports address what other parts of the --

DR. SOKOLOVSKY: Yes.

DR. MILLER: For example, the VA.

DR. SOKOLOVSKY: When we look at Medicaid, we find that physician-billed drugs, Medicaid is not very different from Medicare. The Medicaid rebate does not apply for drugs billed in physician offices.

These drugs really are different. When we look at the VA, it's a very different system because it's an integrated delivery system and they do have a method for tracking what's the lowest priced that any private payer is paying. By statute, they get that price. And then, because it is an integrated delivery system, they are also able to use competitive methods to develop some sorts of formularies in specific diseases categories, make the statement that two drugs are functionally equivalent as CMS has said and then go to the manufacturer and negotiate for a lower price. But they are the direct purchasers, so whatever discounts they can get, the get the benefit of.

DR. MILLER: I only bring that out because I'm sort of left with the reports were saying it's not what the provider pays and there are a couple of other payers, although not necessarily private payers, who can't get a lower price.

MS. DePARLE: I would be interested, if Joan understands, that she could just do a chart which show the various payers, because as I was listening to this it sounds like Medicaid -- Medicaid is entitled to the best price given to a private purchaser, right?

DR. SOKOLOVSKY: The best price at a retail level. And so

for pharmacy supplier drugs they get much better deals than Medicare under Part B.

MS. DePARLE: But the rebate does not apply to many of the drugs that Medicare also pays for because they're given in a physician's office.

DR. SOKOLOVSKY: And you don't buy them --

MS. DePARLE: So Medicaid also is paying more than some other private payers, probably. It's interesting. I don't know if it's possible to reduce this to a chart but I'd be interested in seeing it.

MR. MULLER: My questions are along the same lines that were just discussed by Mark and Glenn and Nancy-Ann, which is one looks at the comparisons of the VA or Medicaid or the big PPMs or even achieved the GPOs in terms of -- in some sense one has different tacks. One is one of just using purchasing volume to get a price, as you point out on the specialty drugs it may be less possible to get that.

Others, as you say, try to do more case management. That's one of the themes I would say certainly of the VA and it may be one of the themes of some of the big private payers in terms of trying to have more disease management as a way of trying to control this.

So I think, in addition to Nancy-Ann's question about trying to get some rough comparison on a scale of 100 or something like that, what does the VA get versus the big GPOs versus Medicaid versus the PBMs, if we could also be looking at the various tactics in some kind of comparative way, are we likely to get more bang for our buck in terms of having some kind of competitive bidding or administered pricing-type mechanism to kind of look at the price of specific drugs? And what proportion of the drugs that are inside the Medicare program would be captured by such a mechanism? It may be you can only capture -- I'll just make up a number -- 50 percent. I don't know what the number is. And then you have to think about how you capture the other 50 percent, not to be wed to those numbers, versus what one can get out of case management.

I think there's a lot of interesting case management work going on around the country. My sense is that -- again, I'm making this number up -- if we push 25 percent of the drugs and case management -- I mean, if we're able to reach 25 percent of the drugs in case management I would be very surprised because I think that's a field that may take many years to unfold.

So looking at the kind of strategies, I think that's covered in your chapter here, would also be helpful as we think about one might do three, four or five years out because certainly the curve on this, on drug costs -- and we discussed this over the last year -- it's not quite as steep as the cost of SNFs in the '90s but it's a very steep one.

So thinking about what one can do in learning from that comparative experience, I think looking at it tactically as well would make a lot of difference.

Thank you.

DR. ROWE: Just a couple of general comments. This is interesting.

I think when we first approached this issue there was some concern (outrage) on the part of some commissioners -- at least myself -- at the difference between what physicians were paying for the drugs and what they were being paid by Medicare, particularly in cases of some oncologists, some of the data that we were at least presented.

And I think that I certainly would not want us to say well, it's okay because the private payers are doing it, too. I mean, I don't think that the message here is if there are these gross disparities, that paying $50 or getting paid $1,000, or whatever the numbers were, if others are paying at also, who also have other arrangements with those physicians and may be paying less for other services or whatever, we shouldn't say well, we should continue to pay these outrageous prices because, after all, others are.

I want to make sure we don't get into that.

MR. HACKBARTH: I agree with that.

DR. ROWE: There may be a little bit of that when we say oh, gee, we checked and everybody else is doing, it's okay, let's go on to the next thing. I think we need to focus on fixing that and finding out what the right price is and paying it and reducing it. And if we're leading the way, for a change, that wouldn't be so bad. And the health plans would be happy to follow. So I would like to see something like that.

The second is at this point I think probably every member of Congress has voted for one or another outpatient prescription drug benefit and it's likely, I guess, and most people think, that some outpatient prescription drug benefit may become law, which I think would be a good thing. And I think it's really important that we make it clear that this is different and that whatever we're doing here isn't Medicare's approach to handling drugs. Now we're going to roll in all the rest of these drugs and oh well, we have an approach to handling drugs, here it is. And that this is really a different species and would be handled very differently, distributed differently, et cetera, et cetera. And there might be just a statement here saying this really doesn't inform any discussion about what system Medicare should set up, whatever that might be, for the usual and customary medications.

DR. NEWHOUSE: Four comments. I've been looking into the cancer drugs for other reasons and what I've been finding out is that it's not very simple to compare Medicare with the private side, that the private side differs by market, that in general if you have a single oncologist in town, he or she can command a higher price than if you have several. The private side just doesn't work the way Medicare does and say we pay 95 percent of something, take it or leave it. So it may not be easy to get a comparison there.

The second point that I'd like to just raise for us to consider is that talking to the oncologists, the oncologists complain that Medicare try to justify their markups in part because Medicare doesn't pay an administration fee. And I'm not sure -- there ought to be some deal here. The markups seem so high that at they're greater than the administrative fees the

private side pays. I've been looking into what the private side pays for administration, too.

And I think if we're going to say something about this, we ought to think about administrative -- paying something for administration. But that would be part of a more general change in payment structure here.

The third point is I'd like to agree with Jack and even strengthen his point about not emulating what the private side is doing. If we do that, we invite distorting the private side because the manufacturer will take into account the fact that Medicare prices going with the private side. This is exactly what happened when Medicaid went in that direction and if Medicaid was to get the lowest available price, the lowest available price went up.

And the fourth thing is just a comment really on Ralph. Bidding is great, and I agree with it, but it only really works if there's a good close substitute. And in a lot of these areas, I think there isn't a good close substitute. So bidding just isn't available. You're kind of stuck with saying this is what we're going to pay, I think. And I'm not sure that -- we've talked about there's not necessarily a very good way to do that. I'd be happy to be wrong on that and think that there was away for bidding to work, but I don't think so.

MS. ROSENBLATT: I think, Joe, the complaint that the oncologists have is not that there is no administration payment. There is one. It's the adequacy of it. And that has been what the debate has been and that is something that Congress has to change. There's been debate and hearings at which the oncologists have testified about that.

Secondly, I'm not quite sure I understand your point about the manufacturer incentives and what impact Medicare's changes might have on the commercial sector pricing. No doubt it may have an effect, but right now I think the point is the manufacturers are offering, in some cases, these drugs to physicians at much lower prices than they offer to others, it appears, to encourage them to prescribe them.

MR. HACKBARTH: The effect may run the other way, that they say we can afford to offer these lower private rates because we know Medicare's going to pay a huge amount for the drugs.

DR. NEWHOUSE: My point was -- I wanted to speak against a policy that Medicare paid X percent above or below 100 of what the private sector paid. There was some effort to link Medicare pricing to what was observed in the private market.

MR. FEEZOR: Just a couple of things. First, Joan I think it's a good coverage of what's going on and certainly the issue of specialty pharmacies is something that, when we recently went out for consideration of a new PBM contractor, was one of the distinguishing characteristics that we looked at in terms of trying to manage our cost.

Two things I'd simply like put on our radar screen. I guess one is increasingly the prospect of genetically tailored pharmaceutical agents and what sort of reasonableness or how you cope with that. So I would just put that up as a question mark for the future.

The other thing, Joan, there is an effort -- and Glenn may speak more to it than I -- about 19 states are trying to put together a consortium in their drug purchasing, both in terms of their state employee programs and even possibly their Medicaid programs being led by a outgoing -- I guess he's now gone, Kitzhoffer in Oregon, some of his folks, growing out of their effort to do effectiveness comparisons and maybe some joint purchasing. And we probably ought to try to monitor that as well.

DR. NELSON: Joan, you mention drugs and biologicals as being separate, but it might be helpful somewhere to use the FDA or some other definition and define drugs and biological because there are some differences. You point out that biologicals are in a rapid growth position and certainly with monoclonal antibodies and things of that sort, I agree with that. I think that's true.

But this also has importance, I believe, because downstream probably we'll deal with this by more explicitly defining the work in administration and managing the patient around the administration of these products. I t may very well be that there's a different kind of work in managing biological administration than drugs. So that definition and distinction would be useful looking forward to that, as well.

DR. WOLTER: I was just going to add -- and it's probably implicit in many of the comments that have already been made -- but an aspect of this has to do also with differential payment in different sites. And if our philosophy over time is to try to not have that -- and this one may be even more difficult than the ASC hospital outpatient discussion, but I think it is part of the analysis we may want to weave in.

MR. HACKBARTH: Anybody else? Okay, thank you, Joan.